

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

<b>IN RE: PHILIPS RECALLED CPAP, BI-</b>	)	
<b>LEVEL PAP, AND MECHANICAL</b>	)	Master Docket: Misc. No. 21-1230
<b>VENTILATOR PRODUCTS</b>	)	
<b>LITIGATION,</b>	)	MDL No. 3014
	)	
<b>This Document Relates to:</b>	)	
	)	
<i>Amended Master Long Form Complaint for</i>	)	
<i>Personal Injuries and Damages, and</i>	)	
<i>Demand for Jury Trial (ECF No. 834)</i>	)	

**PLAINTIFFS' RESPONSE TO PHILIPS RS NORTH AMERICA LLC'S  
OBJECTIONS TO THE SPECIAL MASTER'S REPORT AND  
RECOMMENDATION ON THE MOTION TO DISMISS THE AMENDED  
MASTER LONG FORM COMPLAINT FOR PERSONAL INJURIES**

## **TABLE OF CONTENTS**

TABLE OF AUTHORITIES .....	ii
I. INTRODUCTION .....	1
II. ARGUMENT .....	2
A. Plaintiffs’ Negligent Recall Claim Does Not Implicate Preemption or Primary Jurisdiction (Objection I) .....	2
B. Plaintiffs’ Negligent Failure to Recall Claim Under Illinois and Oklahoma Law Should Not Be Dismissed (Objection II) .....	5
C. Plaintiffs’ Negligence <i>Per Se</i> Claim Should Not be Dismissed (Objection III) .....	6
D. Plaintiffs’ Negligent Misrepresentation Claim Under Minnesota Law Should Not Be Dismissed (Objection IV) .....	8
E. Plaintiffs’ State Consumer Protection Claims Should Survive Philips’ Rule 9(b) Challenge (Objection V) .....	9
F. Plaintiffs’ State Consumer Protection Claims Should Survive Philips’ Objection that the Devices Are Not “Consumer Goods” (Objection VI) .....	10
G. Philips’ Objection Regarding Pre-Suit Notice Should be Rejected (Objection VII) .....	11
H. Plaintiffs’ Negligent Manufacturing Claim Should Not Be Dismissed (Objection VIII) .....	12
I. Plaintiffs’ Express Warranty Claim Should Not Be Dismissed (Objection IX) .....	13
J. The Report Properly Interprets Pennsylvania Law Regarding Comment <i>K</i> (Objection X) .....	14
III. CONCLUSION .....	15

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>Cases</b>	
<i>Abubakari v. Schenker</i> , 2021 WL 1617159 (D. Conn. Apr. 26, 2021) .....	3
<i>Baykeeper v. NL Indus., Inc.</i> , 660 F.3d 686 (3d Cir. 2011).....	4
<i>Brackbill v. Ruff</i> , 2018 WL 2322014 (M.D. Pa. May 22, 2018).....	10
<i>Butela v. Midland Credit Mgmt. Inc.</i> , 341 F.R.D. 581 (W.D. Pa. 2022) .....	3
<i>Cohen v. Johnson &amp; Johnson</i> , 634 F. Supp. 3d 216 (W.D. Pa. 2022).....	15
<i>Craten v. Foster Poultry Farms Inc.</i> , 305 F. Supp. 3d 1051 (D. Ariz. 2018) .....	7
<i>Creazzo v. Medtronic, Inc.</i> , 903 A.2d 24 (Pa. Super. Ct. 2006).....	14
<i>Cummings v. FCA US LLC</i> , 401 F. Supp. 3d 288 (N.D.N.Y. 2019).....	12
<i>D.L. by Friederichs v. Huebner</i> , 329 N.W.2d 890 (Wis. 1983).....	7, 8
<i>Daniel v. Ford Motor Co.</i> , 806 F.3d 1217 (9th Cir. 2015) .....	14
<i>Francis v. Gen. Motors, LLC</i> , 504 F. Supp. 3d 659 (E.D. Mich. 2020).....	11, 12
<i>Gatewood v. Est. of Thompson</i> , 2019 WL 4889161 (D.N.M. Oct. 3, 2019).....	7
<i>Gross v. Coloplast Corp.</i> , 434 F. Supp. 3d 245 (E.D. Pa. Jan. 17, 2020).....	14
<i>Hammick v. Jacobs</i> , 2020 WL 6135464 (D. Or. Oct. 19, 2020).....	7

<i>In re Methyl Tertiary Butyl Ether Prod. Liab. Litig.</i> , 175 F. Supp. 2d 593 (S.D.N.Y. 2001).....	4
<i>In re: Domestic Drywall Antitrust Litig.</i> , 2016 WL 3769680 (E.D. Pa. July 13, 2016).....	2
<i>In re Gen. Motors LLC Ignition Switch Litig.</i> , 154 F. Supp. 3d 30 (S.D.N.Y. 2015).....	6
<i>Javo Beverage Co., Inc. v. Javy Coffee Co.</i> , 2023 WL 387587 (D. Del. Jan. 25, 2023).....	3
<i>Killen v. Stryker Spine</i> , 2012 WL 4498865 (W.D. Pa. Sept. 28, 2012).....	14
<i>Kline v. Zimmer Holdings, Inc.</i> , 2013 WL 3279797 (W.D. Pa. June 27, 2013).....	14
<i>Lance v. Wyeth</i> , 85 A.3d 434 (Pa. 2014).....	14
<i>Moultrie v. Coloplast Corp.</i> , 2020 WL 1249354 (W.D. Pa. Mar. 16, 2020) .....	15
<i>Patchcoski v. W.L. Gore &amp; Assocs., Inc.</i> , 2020 WL 4335016 (M.D. Pa. July 28, 2020).....	14
<i>Pleasant v. McDaniel</i> , 550 S.W.3d 8 (Ark. App. 2018).....	9
<i>Riegel v. Medtronic, Inc.</i> , 552 U.S. 312 (2008).....	4, 5
<i>Schrecengost v. Coloplast Corp.</i> , 425 F. Supp. 3d 448 (W.D. Pa. 2019).....	15
<i>Smith v. BOC Grp. PLC</i> , 2001 WL 477237 (N.D. Ill. May 4, 2001) .....	6
<i>Smith v. Brutger Cos.</i> , 569 N.W.2d 408 (Minn. 1997).....	8
<i>Tincher v. Omega Flex, Inc.</i> , 104 A.3d 328 (Pa. 2014).....	14, 15
<b>Statutes</b>	
21 U.S.C. §§ 360h(b)(1)(A), (b)(2).....	5

21 U.S.C. § 360h(d) .....	1, 4
21 U.S.C. §§ 360h(e) .....	5

## **Rules**

Fed. R. Civ. P 9(b) .....	9
---------------------------	---

## **Other Authorities**

Restatement (Second) of Torts, § 311.....	8
Restatement (Second) of Torts § 402A cmt.B .....	15

## I. INTRODUCTION

Philips RS<sup>1</sup> has raised ten Objections to the Special Master’s Report and Recommendation (ECF 2271) (“Report” or “R&R”) on its Motion to Dismiss Plaintiffs’ Amended Master Long Form and Short Form Complaints for Personal Injuries and Damages.<sup>2</sup> See ECF 2315 (“Objections” or “Obj.”). They each lack merit.

First, Philips objects to the Special Master’s recommendation that Plaintiffs’ negligent recall claims are not preempted or barred by the primary jurisdiction doctrine (Objection I). But Philips misses the mark because it relies upon mischaracterizations of the Report’s findings, ignores the publicly available FDA comments on Philips’ recall efforts, ignores the savings clause in 21 U.S.C. § 360h(d), and downplays the FDA’s authority to order a recall of unsafe medical devices. Upon review, it is clear the Special Master understood Plaintiffs’ negligent recall claim and reached the correct result.

Next, Philips puts forth a litany of objections (Objections II through X) that pick apart specific state-by-state determinations that were made after Philips failed to put forth any meaningful state-by-state analysis or arguments in its Motion to Dismiss. With respect to this group of Objections, Philips complains about the consequences of its own “shotgun” approach to its Motion to Dismiss.<sup>3</sup> Simply put, the reach of Philips’ Motion was far and wide, generally

---

<sup>1</sup> Defendants Philips RS North America LLC (“Philips RS”), Koninklijke Philips N.V., Philips North America LLC, Philips Holding USA Inc., and Philips RS North America Holding Corporation are referred to collectively herein as “Philips.”

<sup>2</sup> Each personal injury action involves a Master Complaint for Personal Injuries and Damages (ECF 834) (“Master Complaint”) and an individual Short Form Personal Injury Complaint (“Short Form Complaint”) that *together* are deemed the operative complaint for each plaintiff. Pretrial Order #28 at §II.B.3. Paragraph (“¶”) and Count citations refer to the Master Complaint. The Master Complaint and Short Form Complaint are collectively referred to as the “Complaint.”

<sup>3</sup> The R&R addresses Philips RS’s Motion to Dismiss Plaintiffs’ Amended Master Long Form and Short Form Complaints for Personal Injuries (ECF 1345) (the “Motion to Dismiss” or “Motion”). The remaining Philips’ entities joined in that Motion (ECF 1359 at 4 n.3). Philips RS’s Opening

challenging numerous states' laws with respect to many causes of actions even where the law was clearly not in its favor and often with little or no substantive analysis as to the law of these challenged jurisdictions. *See, e.g.*, Opp. at 20-22, 26 n.33, 33-37; 7/10/2023 Tr.<sup>4</sup> at 22:10-12 (Plaintiffs "envision[ed] . . . with regard to a dismissal motion on the Master Complaint . . . general crosscutting issues"), 33:6-10 ("the Court is being asked to render advisory opinions on the laws of 50 states, . . . without a record that's developed in each of those cases"), 156:22 ("So for 15 jurisdictions, they only cite a statute."), 195:13-24 ("they cited four cases, but they didn't point to any particular state's law. . . ."). Having provided the Special Master with little guidance as to the substance of its arguments, Philips now complains that the Special Master misapprehended Philips' position simply because his independent analysis did not reach Philips' desired result. *See In re: Domestic Drywall Antitrust Litig.*, 2016 WL 3769680, at \*11 (E.D. Pa. July 13, 2016) ("To the extent Defendants' one-paragraph argument is an invitation for the Court to comb through all of Plaintiffs' consumer protection claims and determine whether the elements have been adequately pleaded, the Court respectfully declines the invitation.").

## **II. ARGUMENT**

### **A. Plaintiffs' Negligent Recall Claim Does Not Implicate Preemption or Primary Jurisdiction (Objection I)**

Philips objects to the Special Master's finding that Plaintiffs' negligent recall claim is not preempted or barred by the primary jurisdiction doctrine. Obj. at 2-3; R&R at 21-28.

*First*, Philips suggests that the Special Master was confused by the fact that Plaintiffs'

---

Brief in Support of that Motion (ECF 1346) is referred to herein as "Opening Brief" or "Br." and its Reply Brief in Support of that Motion (ECF 1827) is referred to herein as "Reply." Plaintiffs' Opposition to the Motion (ECF 1643) is referred to herein as "Opposition" or "Pls. Opp."

<sup>4</sup> The July 10, 2023 transcript is attached to Plaintiffs' Objections to the R&R (ECF 2313) ("Plaintiffs' Objections" or "Pls. Obj.") as Exhibit "A" (ECF 2313-1) ("7/10/2023 Tr.").

negligent recall claim has two components alleged in a single count.<sup>5</sup> *Id.* at 2. There is no confusion that Plaintiffs alleged both negligent failure to recall (*i.e.*, failing to recall the Devices when Philips became aware of the defect), *see* ¶¶ 412-20, and negligent recall (*i.e.*, negligently conducting the recall once a decision was made to recall the Devices), *see* ¶¶ 412-13, 421-28. Even though Philips argues now that its preemption argument relates to Plaintiffs’ negligent *failure to recall* claim, Obj. at 3, it initially argued that the claims were preempted because Plaintiffs cited the FDA’s 518(a) Order and 518(b) Notice, Br. at 15, which only related to Plaintiffs’ negligent recall claim. ¶¶ 191-92, 412. The Special Master’s citation to these allegations was to directly address arguments made by Philips, R&R at 21-22, not because of confusion, Obj. at 2.

**Second**, Philips argues that there is a mistaken assumption underlying the Special Master’s findings that the FDA has made a “determination” with respect to the recall. Obj. at 2-3 (citing R&R at 26). Philips points to the Special Master’s statement that the FDA has “determined” that “a recall of the Devices is warranted” and “that the Recalled Devices . . . do not comply with CGMP.” Obj. at 2 (citing R&R at 26). But these two statements are clearly true based upon the FDA’s pronouncements cited in the Complaint.<sup>6</sup> *See, e.g.*, Compl., Ex. 72 (FDA 518(b) Notice); Ex. 136 (FDA 518(a) Order); ¶¶ 125-26 (regarding GMP); ¶¶ 191-94, 300 (FDA notice regarding the recall); ¶¶ 286-90, 423 (FDA describing inadequacy of Philips’ recall efforts).

**Primary Jurisdiction.** Philips’ objection to the Special Master’s primary jurisdiction

---

<sup>5</sup> There is nothing improper about including two claims in a single count. Pls. Obj. at 8 & n.10; *see also Javo Beverage Co., Inc. v. Javy Coffee Co.*, 2023 WL 387587, at \*2 (D. Del. Jan. 25, 2023); *Abubakari v. Schenker*, 2021 WL 1617159, at \*3 (D. Conn. Apr. 26, 2021); *Butela v. Midland Credit Mgmt. Inc.*, 341 F.R.D. 581, 592 (W.D. Pa. 2022).

<sup>6</sup> As recently as October 5, 2023, the FDA has reiterated that it is dissatisfied with Philips’ recall. *See, e.g.*, Toby Sterling and Piotr Lipinski, “US FDA still not satisfied with Philips recall; stock falls over 9%,” *Reuters*, available at <https://www.reuters.com/business/healthcare-pharmaceuticals/fda-says-it-is-not-satisfied-with-philips-breathing-device-recall-2023-10-06/> (last accessed Nov. 26, 2023).



finding does little more than reargue the *Baykeeper*<sup>7</sup> factors. *See* Obj. at 2-3; Opp. At 17-18. The weight of Philips’ argument relies on its mischaracterization of the Special Master’s treatment of the FDA action with respect to the recall. Philips does not dispute the Special Master’s findings that “[w]hether Respironics failed to act with reasonable care in undertaking the recall is the type of issue that falls squarely with the conventional experience of judges,” R&R at 26 (first *Baykeeper* factor), and “the key issues in the negligent recall claim are whether Respironics had a duty and whether [it] violated that duty—issue[s] well within the domain of the court,” *id.* (second *Baykeeper* factor). These core findings illustrate why the Special Master’s recommendation was correct.<sup>8</sup>

Philips also objects that the Special Master improperly cited to the savings clause in 21 U.S.C. § 360h(d) with respect to the third *Baykeeper* factor. Obj. at 3. The Special Master’s citation to this provision was not controlling, but even if it were, it evidences Congressional intent that liability was not to be exclusively federal. R&R at 27. Moreover, Philips overstates the Supreme Court’s opinion in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 n.4 (2008). In *Riegel*,<sup>9</sup> the Supreme Court did not “reject[] an overly broad reading of Section 360h(d)” but instead reached the unremarkable conclusion that reading the savings clause to mean that *no* state-law claims were preempted would render the MDA’s express preemption provision meaningless. *Id.* This does not diminish that Congress expressed the clear intent for there to be liability for recall-related claims under state law. 21 U.S.C. § 360h(d); *see also Riegel*, 552 U.S. at 325 n.4 (Ginsberg, *dissenting*).

---

<sup>7</sup> *Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 691 (3d Cir. 2011) (Vanaskie, J.).

<sup>8</sup> Abstention on primary jurisdiction grounds is rare, *see Baykeeper*, 660 F.3d at 691, and “courts generally do not defer jurisdiction where plaintiffs seek injury to their property or person.” *In re Methyl Tertiary Butyl Ether Prod. Liab. Litig.*, 175 F. Supp. 2d 593, 618 (S.D.N.Y. 2001).

<sup>9</sup> Philips cites almost exclusively cases dealing with express preemption. The issue here is one of implied preemption, not express preemption.

**Preemption.** Philips’ objection to the Special Master’s recommendation on preemption is similarly misguided. Philips argues that Plaintiffs’ negligent failure to recall claim seeks to impose a mandatory recall when the FDA regulations only call for a voluntary recall and, therefore, such a requirement would be “in addition to” those imposed by federal law. Obj. at 3. As the Special Master properly determined, because this is an implied preemption case, the claims are not preempted so long as they are rooted in state law duties and those state law duties are consistent with federal duties (this is a conflict preemption case and there is no preemption unless complying with state law duties conflicts with federal obligations). R&R at 18-19. Here, the FDA has substantial authority to act when “a device ‘presents an unreasonable risk of substantial harm to the public health’ and that notice of the defect ‘would not . . . eliminate the unreasonable risk.’” *Riegel*, 552 U.S. at 338-39 (citing 21 U.S.C. §§ 360h(b)(1)(A), (b)(2), (e)) (Ginsberg, *dissenting*). In that circumstance, “the FDA may order the manufacturer to repair the device, replace it, refund the purchase price, cease distribution, **or recall the device.**” *Id.* (emphasis added). Therefore, any state court finding that Philips’ failure to recall the Devices after learning they were defective and posed a substantial health risk to customers was negligent would not be based on obligations under federal law but on state law duties that are not in conflict with federal law.

**B. Plaintiffs’ Negligent Failure to Recall Claim Under Illinois and Oklahoma Law Should Not Be Dismissed (Objection II)**

Philips objects that the Special Master should have recommended dismissal of Plaintiffs’ negligent failure to recall claim under Illinois and Oklahoma law. Obj. at 4. In its Opening Brief, Philips devoted only one paragraph to arguing for dismissal of Plaintiffs’ negligent failure to recall claim under the laws of ten states, relying mostly on a string cite of cases with no parentheticals in its Table A(1). Br. at 18 & Table A(1). The R&R shows that the Special Master reviewed Philips’ two relevant cases—one from Illinois and one from Oklahoma—and those cited by Plaintiffs and

found that Philips’ argument lacked merit. R&R at 37-38; *see* Opp. at 19 & Chart-1. Once again, Philips barely offers an argument. Obj. at 4.

Instead, Philips’ lone attack is on the authority cited by Plaintiffs and relied on by the Special Master that Philips argues concerns only a “general negligence claim.” Obj. at 4 (emphasis removed). However, *Smith v. BOC Grp. PLC*, concerned a claim that “Defendants acted negligently in . . . *failing to recall these products*.” 2001 WL 477237, at \*5 (N.D. Ill. May 4, 2001) (emphasis added). And *In re Gen. Motors LLC Ignition Switch Litig.* concerned a claim for negligent “*delay in recalling*” defective products. 154 F. Supp. 3d 30, 44 (S.D.N.Y. 2015) (emphasis added). Thus, both concern the same type of claim Plaintiffs assert here and the Special Master’s evaluation of Illinois and Oklahoma law was sound.

### **C. Plaintiffs’ Negligence *Per Se* Claim Should Not be Dismissed (Objection III)**

Philips objects that the Special Master did not properly analyze whether negligence *per se* is a recognized cause of action under nine jurisdictions’ laws.<sup>10</sup> Obj. at 4-5. Philips argues that the Special Master failed to analyze the law of seven states, but Philips itself performed no such analysis. Br. at 38-39. Instead, Philips committed a single paragraph in its Opening Brief to argue for dismissal of claims from 26 states, relying mostly on a string cite of cases in its Table G(1) with no parentheticals or explanation of each case’s relevance. *Id.* & Table G(1). Philips’ Objections also offer almost no analysis. Obj. at 4-5.

Philips does not contend that negligence *per se* is not a viable theory under these jurisdictions’ laws; Philips contends only that negligence *per se* must be asserted in relation to a negligence cause of action, not as a separate cause of action. Br. at 38-39. Philips does not explain

---

<sup>10</sup> Those nine jurisdictions are: Arizona, Arkansas, Maine, Nebraska, New Mexico, Oregon, Rhode Island, Utah, and Wisconsin.

why this distinction makes any practical difference as negligence *per se* under the laws of these nine jurisdictions will remain in the case regardless of what the Court finds. Opp. at 39. Philips provides minimal, if any, substantive discussion on this issue. Obj. at 4-5.

**Arizona.** Under Arizona law, negligence *per se* is not a separate cause of action from negligence, but it may be pleaded separately. *See Craten v. Foster Poultry Farms Inc.*, 305 F. Supp. 3d 1051, 1054 & n.2, 1064-65 (D. Ariz. 2018) (denying summary judgment on separately pleaded negligence and negligence *per se* counts).

**Arkansas, Maine, Nebraska, Rhode Island, and Utah.** Philips contends that under the laws of these states, the violation of a statute is evidence of negligence rather than negligence *per se*. *See* Obj. at 5. This argument goes to the evidentiary standards for negligence and negligence *per se*, not whether negligence *per se* can be pleaded as a separate claim. The Report’s conclusion that Arkansas law “integrate[s] negligence *per se* claims into basic negligence claims, but do[es] not mandate that separately pled negligence *per se* claims be dismissed for that reason[.]” R&R at 43, applies with equal force to the laws of all five of these states.

**New Mexico and Oregon.** Without substantive discussion, Philips cites one case for each of these states. Each of the two cases contain a separately pleaded negligence *per se* claim that was dismissed on the ground that negligence *per se* should not be separately pleaded. *See Gatewood v. Est. of Thompson*, 2019 WL 4889161, at \*2 (D.N.M. Oct. 3, 2019) (“the Court will evaluate Plaintiffs’ claim against Defendant Kays both under an ordinary negligence standard and according to a theory of negligence *per se*.”); *Hammick v. Jacobs*, 2020 WL 6135464, at \*1 (D. Or. Oct. 19, 2020) (denying summary judgment regarding “claims for common law negligence and negligence *per se*”).

**Wisconsin.** Without substantive discussion, Philips relies on *D.L. by Friederichs v.*

*Huebner*, 329 N.W.2d 890, 917 (Wis. 1983), which defines negligence *per se* and distinguishes it from absolute liability but says nothing to suggest that negligence *per se* is not a viable claim.

**D. Plaintiffs’ Negligent Misrepresentation Claim Under Minnesota Law Should Not Be Dismissed (Objection IV)**

Philips objects to the Special Master’s recommendation that the Motion to Dismiss negligent misrepresentation under Minnesota law be denied. Obj. at 5-6. Philips, having devoted a total of two sentences and a few Case Citation Tables to this issue, now complains that the Special Master’s thoughtful and lengthy analysis fails to comprehend Philips’ argument. *Id.*; *see also* Br. at 32-33 & Tables E(3) and E(4); *see also* Reply Table C(2). In fact, Philips contends that the Special Master mischaracterized its argument by saying that Philips was arguing that a negligent misrepresentation claim “is only available in the context of a business relationship in Minnesota,” Obj. at 5 (quoting R&R at 61), when Philips’ own Case Citation Table on the topic was titled “Jurisdictions that limit negligent misrepresentation cause of action *to business transactions*,” Table E(4) (emphasis added).

But the Special Master correctly acknowledged that the law in Minnesota on this issue is unclear. As Plaintiffs argued, the Minnesota Supreme Court has neither adopted nor rejected Restatement (Second) of Torts, § 311 dealing with “Negligent Misrepresentation Involving Risk of Physical Harm.” Opp. at 32 & Chart-8; *see also Smith v. Brutger Cos.*, 569 N.W.2d 408, 414 (Minn. 1997) (“While we do not foreclose the possibility of recognizing in Minnesota the tort of negligent misrepresentation involving the risk of physical harm, we decline to do so today.”). In addition, some cases have allowed a negligent misrepresentation claim in certain circumstances. *E.g.*, R&R at 61. And, the factual premise of Philips’ argument is flawed because pecuniary loss can still exist in the personal injury context (*e.g.*, medical bills, lost wages, etc.). ¶ 592 (“compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys’

fees, and such other relief as the Court deems equitable and just”). The Special Master was correct to determine that the “lack of clarity” in the governing law and “the deferential standard of a motion to dismiss” weighed in favor of recommending against dismissal. R&R at 61.

**E. Plaintiffs’ State Consumer Protection Claims Should Survive Philips’ Rule 9(b) Challenge (Objection V)**

Philips objects that the Special Master should have recommended dismissal of all of the consumer protection claims under Fed. R. Civ. P 9(b) for failure to plead fraud with particularity. Obj. at 6. Philips’ argument is flawed in the first instance. As explained in Plaintiffs’ Objections, the Report wrongly recommended dismissal of Plaintiffs’ fraud claims because, among other things, it failed to appreciate that Plaintiffs alleged fraud by omission. Pls. Obj. at 3-7. To the extent that any of the state consumer protection statutes at issue sound in fraud, and therefore, require satisfaction of Rule 9(b), Plaintiffs satisfied that standard. *See, e.g., id.*; Opp. at 34.

Unlike claims of common law fraud, however, claims under state consumer protection statutes are rooted in separate statutes enacted in the individual states. While the elements of these claims largely overlap because they are based on uniform statutes, Opp. at 33, the substantive law governing each statute determines whether such a claim sounds in fraud, and simply put, not all state consumer protection claims sound in fraud. *See* R&R at 76 n.11; *see, e.g., Pleasant v. McDaniel*, 550 S.W.3d 8, 12 (Ark. App. 2018) (as an ADTPA action is “not a ‘fraud’ action, Rule 9(b) is not the proper pleading standard). So, before compliance with Rule 9(b) is evaluated, Philips must first establish that Rule 9(b) applies to particular consumer protection statutory claims.

Philips casts blame on the Special Master for not conducting a jurisdiction-specific analysis, Obj. at 7, but Philips itself made no such effort. Philips devotes two sentences to this argument in its Opening Brief with citation only to the false advertising laws of two states—Minnesota and Florida. *See* Br. at 33 & n.39. In total, between its Opening Brief, Reply and oral

argument, Philips only referenced the laws of a mere six of the more than 50 jurisdictions at issue. *See id.*; Reply at 23; 7/10/2023 Tr. at 169:24-170:8. Philips attempts to remedy this problem with a string cite in a footnote in its Objections that offers no context or argument. Obj. at 7-8 n.8. This woefully underdeveloped argument based on nothing more than Philips’ *ipse dixit* should be rejected. *See Brackbill v. Ruff*, 2018 WL 2322014, at \*6 (M.D. Pa. May 22, 2018) (declining to address underdeveloped argument).

**F. Plaintiffs’ State Consumer Protection Claims Should Survive Philips’ Objection that the Devices Are Not “Consumer Goods” (Objection VI)**

Philips objects that the Special Master erred in rejecting its argument that the Recalled Devices—personal use products that sit by a person’s bedside—are outside the scope of the term “consumer goods” under the consumer protection statutes of 24 jurisdictions. Obj. at 8. Even though these statutes are individual state laws, Philips makes no effort to explain how any state’s law is inconsistent with the Special Master’s analysis and instead falls back on citation to its prior briefing which itself failed to meaningfully address the separate laws of these jurisdictions. *Id.*

In support of its inadequately developed argument, Philips relies on nothing more than the statutes’ language that they apply to “goods or services for personal, family, or household use,” Obj. at 8, even though that argument only begs the question of whether the Recalled Devices constitute “goods for personal use,” under a particular state’s law. There is no basis to conclude that the Recalled Devices fall outside of the plain language meaning of “goods for personal use,” such that the issue should be decided in Philips’ favor. *See, e.g.,* Opp. at 35-36 & Chart-15.

The Report analyzes the core question of whether the Devices are “consumer goods” under these statutes by conducting a jurisdiction-by-jurisdiction analysis and carefully addressing and rejecting Philips’ narrow and unsupported construction of the law. R&R at 92-105. Instead of accepting that result, Philips blames the Special Master for failing to conduct an appropriate

analysis when the jurisdiction-by-jurisdiction analysis in the Report is vastly more detailed than anything Philips presented in its papers. Br. at 35 & Table F(7); Reply at 21. Simply put, this is another example where Philips made an undeveloped argument with little support, and then was dissatisfied when the Special Master ruled against it. As shown by Plaintiffs' briefing and the Special Master's fulsome analysis, Philips is wrong on the law.

**G. Philips' Objection Regarding Pre-Suit Notice Should be Rejected (Objection VII)**

Philips objects to the Special Master's finding that whether Plaintiffs have adequately provided pre-suit notice with respect to Plaintiffs' warranty claims and consumer protection claims in certain states, is a question of fact to be determined after discovery. Obj. at 9-10; R&R at 112-13. To date, Philips has done nothing more than make bold and conclusory statements about the type of notice provided and has not attempted to discuss whether any exceptions to those state-specific notice requirements apply. Philips casts blame on the Special Master, claiming he "mischaracterizes" its argument as challenging the sufficiency of the notices, Obj. at 9, when, in fact, that is one of two arguments Philips made with respect to the notice, Br. at 36 ("the letters were neither sent pre-suit *nor compliant with the relevant statutes*"). After failing to analyze the law of each of these states, Philips' criticism of the Special Master is unwarranted. *See Francis v. Gen. Motors, LLC*, 504 F. Supp. 3d 659, 691-92 (E.D. Mich. 2020) (explaining that "caution is called for" in addressing underdeveloped argument).

Plaintiffs have consistently argued that this issue is a factual question not best decided on a motion to dismiss because each of the states that Philips claims have unsatisfied notice requirements provide for many forms of notice and also contain exceptions to the notice requirement. *See* Opp. at 25-26, 36-37 & Chart 17. Philips is simply trying to have the Court improperly make an evidentiary ruling at this early stage as to the sufficiency of notice and the



applicability of any exceptions thereto. *See Francis*, 504 F. Supp. 3d at 691-92.

Philips does not raise the larger issue discussed at oral argument with respect to notice requirements in the context of a Master Complaint. *See* 7/10/2023 Tr. at 164:12-167:9. Here, even the letters Philips cites were sent prior to the filing of the Master Complaint, and if Philips' argument were to be accepted, either no Plaintiff could bring these claims because the first Plaintiff to file an action failed to comply with pre-suit notice requirements or every individual Plaintiff who filed a Short Form Complaint would need to individually and independently serve pre-suit notice prior to filing its Complaint, which would be horribly inefficient and defeat the purpose of the processes set up for filing streamlined Complaints in this MDL. *Id.*

#### **H. Plaintiffs' Negligent Manufacturing Claim Should Not Be Dismissed (Objection VIII)**

Philips objects that the Special Master erred in recommending against dismissal of Plaintiffs' negligent manufacturing claim because, according to Philips, violation of good manufacturing practices and related duties is insufficient to state a claim for negligent manufacturing. Obj. at 10-12; *see also* Br. at 28-29. Plaintiffs have argued that the Complaint adequately alleges a negligent manufacturing claim because it lays out in detail not only Philips' conduct with respect to the Recalled Devices and the injuries flowing from that conduct, but also how the manufacturing of the Devices violated federal and state duties and otherwise fell below reasonable standards. *See* Opp. at 30-31. In addition, Plaintiffs argued that manufacturing defect claims are better decided after discovery, as "information related to the manufacturer's intention is within the sole possession of the manufacturer." *Cummings v. FCA US LLC*, 401 F. Supp. 3d 288, 314 (N.D.N.Y. 2019). At oral argument, the Special Master summed it up well asking counsel for Philips: "Could you construct an argument that they have to comply with sound manufacturing practices or good manufacturing practices, and that requires that they do adequate testing of

materials that they incorporate into their product and they were negligent in testing the materials so that goes to manufacturing negligence and manufacturing[?]" 7/11/2023 Tr., attached hereto as Exhibit "A," at 19:21-20:2. Ultimately, the Special Master correctly agreed with Plaintiffs, allowing the negligent manufacturing claim to proceed while discovery is ongoing.

### **I. Plaintiffs' Express Warranty Claim Should Not Be Dismissed (Objection IX)**

Philips objects to the Special Master's recommendation that Plaintiffs' express warranty claims should survive, by falling back on its argument, repeated throughout its briefing, that the warranty at issue is for "workmanship and materials," which, according to Defendant, excludes design defect claims. Obj. at 12-14; Br. at 19-20; Reply at 6-7. Legally, Philips' argument is flawed. Philips' Opening Brief made no specific state-by-state argument, instead relying on the premise that this "workmanship and materials" rule was inviolate. When Plaintiffs pointed out that not all state laws drew such a distinction, Opp. at 21-22, Philips responded with a Table citing nine cases with no explanation or parentheticals that supposedly addressed the law of 43 jurisdictions, Reply at 6 n.5 & Reply Table A(1). Philips did not develop this argument, and Plaintiffs had no opportunity to meaningfully respond. 7/10/2023 Tr. at 195:3-196:6.

Notwithstanding the undeveloped argument, the Special Master properly found that determining the scope of the defect was best left for after discovery. R&R at 122-24. For the reasons discussed in Section II.H above, the Special Master's determination was sound. Regardless, the factual deficiency in Philips' argument mainly addresses the import and meaning of language in the warranty itself. *Id.* The warranty went beyond just "workmanship and materials," because Philips actually warranted that the Devices "will perform in accordance with the product specifications" which, in Plaintiffs' view, indicated a representation with respect to design defect. Opp. at 21-22. In addition, at oral argument, it was discussed how the language of

the warranty was incessantly caveated making it impossible for a reasonable person to determine if the limitations therein even applied to them. *E.g.*, 7/10/2023 Tr. at 197:2-7 (after claiming it did not apply to liability for, among other things, consequential damages, the warranty states that “[s]ome states do not allow the exclusion or limitation of incidental or consequential damages. So the above limitation or exclusion may not apply to you.”). These ambiguities should be resolved against Philips. *See Daniel v. Ford Motor Co.*, 806 F.3d 1217, 1225 (9th Cir. 2015).

**J. The Report Properly Interprets Pennsylvania Law Regarding Comment K (Objection X)**

Philips objects to the Special Master’s determination that Pennsylvania law would not bar strict liability claims involving prescription medical devices based on comment *k*. Obj. at 14-15; *see also* R&R at 140-41, 148-49. Simply put, the Special Master accepted Plaintiffs’ well-reasoned position that Philips was relying upon old caselaw that failed to account for recent developments in Pennsylvania law. R&R at 148-49. Philips repeats that mistake in its Objections. Obj. at 14-15.

Philips’ argument is rooted in this Court’s prior decisions in *Killen v. Stryker Spine*, 2012 WL 4498865 (W.D. Pa. Sept. 28, 2012) and *Kline v. Zimmer Holdings, Inc.*, 2013 WL 3279797 (W.D. Pa. June 27, 2013). As Plaintiffs explained and the Special Master understood, there have been significant developments in the law since the Court’s decisions in those case. Opp. at 26-28. *Killen* and *Kline* were based on an opinion from the Pennsylvania Superior Court, *Creazzo v. Medtronic, Inc.*, 903 A.2d 24 (Pa. Super. Ct. 2006), that has been subsequently called into question. *See, e.g., Gross v. Coloplast Corp.*, 434 F. Supp. 3d 245, 250-51 (E.D. Pa. Jan. 17, 2020) (referring to *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 396 (Pa. 2014) and *Lance v. Wyeth*, 85 A.3d 434, 452 n.21 (Pa. 2014)). These cases “undermine *Creazzo*’s persuasive force and suggest that the Pennsylvania Supreme Court would not apply comment *k* to categorically exempt all prescription medical devices from strict liability claims.” *Patchcoski v. W.L. Gore & Assocs., Inc.*, 2020 WL

4335016, at \*9 (M.D. Pa. July 28, 2020).

Chief Judge Hornak recently recognized the importance of *Tincher* and *Lance* when he declined to follow *Creazzo* and held that, in light of *Tincher* and *Lance*, the Pennsylvania Supreme Court “likely would conclude that strict liability claims are cognizable against medical device manufacturers, and that the extension of comment *k* to bar strict liability claims may only apply as to certain medical devices and only when as evaluated on a case-by-case basis and only after consideration of the full and developed factual record.” *Cohen v. Johnson & Johnson*, 634 F. Supp. 3d 216, 228 (W.D. Pa. 2022) (Hornak, J.). Contrary to Philips’ argument, Judge Hornak engaged in a thoughtful analysis of the applicable law and reached a conclusion consistent with that of other judges in this district who have analyzed comment *k* in light of *Tincher* and *Lance*. See *Moultrie v. Coloplast Corp.*, 2020 WL 1249354, at \*10 (W.D. Pa. Mar. 16, 2020) (Dodge, J.); *Schrecengost v. Coloplast Corp.*, 425 F. Supp. 3d 448, 465 (W.D. Pa. 2019) (Gibson, J.).

Finally, contrary to Philips’ argument, Obj. at 15, the Report does not improperly expand liability under Pennsylvania law in violation of the *Erie* doctrine. The Pennsylvania Supreme Court has explained that under Pennsylvania law “[n]o product is expressly exempt [from strict liability] and, as a result, the presumption is that strict liability may be available with respect to any product, provided that the evidence is sufficient to prove a defect.” *Tincher*, 104 A.3d at 382 (citing Restatement (Second) of Torts § 402A cmt. B). Thus, where no immunity from strict liability exists under the common law, or where the Pennsylvania legislature has not created immunity, “the default general rule of possible liability operates.” *Id.* at 396 (internal citation omitted).

### **III. CONCLUSION**

For the foregoing reasons, Plaintiffs respectfully request that the Court overrule Philips’ Objections and adopt the Report and Recommendation with the exceptions set forth in Plaintiffs’ Objections.

DATED: November 30, 2023

Respectfully submitted,

/s/ Sandra L. Duggan  
Sandra L. Duggan, Esquire  
**LEVIN SEDRAN & BERMAN LLP**  
510 Walnut Street, Suite 500  
Philadelphia, PA 19106  
(215)592-1500 (phone)  
[sduggan@lfsblaw.com](mailto:sduggan@lfsblaw.com)

/s/ Christopher A. Seeger  
Christopher A. Seeger, Esquire  
**SEEGER WEISS LLP**  
55 Challenger Road, 6th Floor  
Ridgefield Park, NJ 07660  
(973) 639-9100 (phone)  
[cseeger@seegerweiss.com](mailto:cseeger@seegerweiss.com)

/s/ Steven A. Schwartz  
Steven A. Schwartz, Esquire  
**CHIMICLES SCHWARTZ KRINER &  
DONALDSON-SMITH LLP**  
361 West Lancaster Avenue  
One Haverford Centre  
Haverford, PA 19041  
(610) 642-8500 (phone)  
[steveschwartz@chimicles.com](mailto:steveschwartz@chimicles.com)

/s/ Kelly K. Iverson  
Kelly K. Iverson, Esquire  
**LYNCH CARPENTER, LLP**  
1133 Penn Avenue, 5th Floor  
Pittsburgh, PA 15222  
(412) 322-9243 (phone)  
[kelly@lcllp.com](mailto:kelly@lcllp.com)

*Plaintiffs' Co-Lead Counsel*

/s/ D. Aaron Rihn  
D. Aaron Rihn, Esquire  
**ROBERT PEIRCE & ASSOCIATES,  
P.C.**  
707 Grant Street, Suite 125  
Pittsburgh, PA 15219  
(412) 281-7229 (phone)  
(412) 281-4229 (fax)  
[arihn@peircelaw.com](mailto:arihn@peircelaw.com)

Peter St. Tienne Wolff, Esquire  
**PIETRAGALLO GORDON ALFANO  
BOSICK & RASPANTI, LLP**  
One Oxford Centre - 38th Floor  
Pittsburgh, PA 15219  
(412) 263-2000 (phone)  
(412) 263-2001 (fax)  
[psw@pietragallo.com](mailto:psw@pietragallo.com)

*Plaintiffs' Co-Liaison Counsel*

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing document was filed via the Court's CM/ECF system on November 30, 2023, and is available for download by all counsel of record.

/s/ D. Aaron Rihn

D. Aaron Rihn

PA I.D. No.: 85752

ROBERT PEIRCE & ASSOCIATES, P.C.

707 Grant Street

Suite 125

Pittsburgh, PA 15219

Tel: 412-281-7229

Fax: 412-281-4229

arih@peircelaw.com